June 11, 2026

Synthes (USA) Products, LLC
Mitchel Bartko
Regulatory Affairs Specialist III
1301 Goshen Pkwy.
West Chester, Pennsylvania 19380

Re: K254087
Trade/Device Name: MAXFRAME AUTOSTRUT with Bluetooth Multi-Axial Correction System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Codes: KTT, OSN
Dated: May 13, 2026
Received: May 13, 2026

Dear Mitchel Bartko:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2026.06.11 18:21:27 -04'00'

for Lixin Liu, Ph.D.
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254087

Please provide the device trade name(s).

MAXFRAME AUTOSTRUT™ with Bluetooth Multi-Axial Correction System

Please provide your Indications for Use below.

The MAXFRAME AUTOSTRUT™ with Bluetooth Multi-Axial Correction System is indicated for the following treatments in adults, and in both children (3–12) and adolescents (12–21) in which the growth plates have fused or will not be crossed with hardware:

- fracture fixation (open and closed)
- pseudoarthrosis of long bones
- limb lengthening (epiphyseal or metaphyseal distraction)
- joint arthrodesis
- infected fractures or nonunions
- correction of bony or soft tissue deformities
- correction of segmental defects

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(K) SUMMARY

Sponsor	Synthes (USA) Products, LLC 1301 Goshen Parkway West Chester, PA 19380
Contact	Mitchel Bartko Regulatory Affairs Specialist III T: +1 908 808 6541 E: mbartko1@ITS.JNJ.com
Alternate Contact	Jeffrey Krawiec, PhD Senior Regulatory Affairs Program Lead T: +1 484 816 6858 E: jkrawiec@its.jnj.com
Date Prepared	May 7, 2026
Proprietary Name	MAXFRAME AUTOSTRUT™ with Bluetooth Multi-Axial Correction System
Classification Name	Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Classification	Class II Regulation Numbers: 21 CFR §888.3030 Product Codes: KTT; OSN
Predicate Device	Traditional 510(k) submission with the following predicate devices: • K202810 - AutoStrut G2 • K211313 - MAXFRAME Multi-Axial Correction System (aka MAXFRAME)
Device Description	MAXFRAME AUTOSTRUT™ with Bluetooth Multi-Axial Correction System consists of an automated hexapod control system kit with Bluetooth functionality, accessories, MAXFRAME™ 3 Software (a web-based software) and MAXFRAME AUTOSTRUT™ Mobile Application (App) to build an automated external fixation frame for the treatment of soft tissue and bone deformities. Additionally, it is used with hardware components from the MAXFRAME Multi-Axial Correction System and the MAXFRAME AUTOSTRUT System which information on these systems can be found in IFU GP3026 and IFU GP3150, respectively. MAXFRAME AUTOSTRUT with Bluetooth Control System is MR Unsafe. The MAXFRAME AUTOSTRUT with Bluetooth Multi-Axial Correction System is only compatible with the DePuy Synthes MAXFRAME and MAXFRAME AUTOSTRUT Systems. The MAXFRAME AUTOSTRUT with Bluetooth Multi-Axial Correction System with Adult and Pediatric indications is an external ring fixation system that is combined with MAXFRAME 3 Software (web-based) and MAXFRAME AUTOSTRUT Mobile App in treatment of soft tissue and bone deformities. In the MAXFRAME AUTOSTRUT with Bluetooth Multi-Axial Correction System, implanted transfixion wires, Schanz screws and pins are attached to the rings and plates surrounding the deformity using bolts, nuts and connecting plates. Upper and lower rings are then connected to one another using six telescoping struts, creating a “Stewart Platform” type device. Adjusting the strut length

	allows for correction of length, rotation, and angular deformity at the same time. The modular nature of a ring fixation frame allows multiple frame options. A ring fixation frame is assembled individually by the surgeon to address the different characteristics of each case.
Indications for Use	The MAXFRAME AUTOSTRUT with Bluetooth Multi-Axial Correction System is indicated for the following treatments in adults, and in both children (3-12) and adolescents (12-21) in which growth plates have fused or will not be crossed with hardware: • fracture fixation (open and closed) • pseudoarthrosis of long bones • limb lengthening (epiphyseal or metaphyseal distraction) • joint arthrodesis • infected fractures or nonunions • correction of bony or soft tissue deformities • correction of segmental defects
Contraindications	The MAXFRAME AUTOSTRUT with Bluetooth Multi-Axial Correction System is not intended for use in the spine.
Non-Clinical Performance Testing	To demonstrate the safety and efficacy of the subject devices and support the substantial equivalence to their predicates, the following testing was performed: • Software Testing as Part of Verification & Validation • Cybersecurity Testing (e.g. penetration testing) • Electrical Magnetic Compatibility (EMC) Testing per IEC 60601 • Radiated Susceptibility (RS) Testing per RTCA DO-160, Section 20.5 • Electrical Safety Testing per IEC 60601 • IP 58 Testing (ingress protection) • Operational Temperature Testing • System Reliability Testing Note: Magnetic Resonance (MR) testing was not provided as the device is MR Unsafe which is unchanged from the predicate device.
Clinical Performance Data	Clinical testing was not necessary for the determination of substantial equivalence.
Substantial Equivalence	The subject devices have the same intended use and indications as their predicate devices. Additionally, the subject devices are an iteration on the predicate device to include wireless (Bluetooth) functionality and the development of software applications to facilitate that functionality. Therefore, the fundamental design, technology, materials, and use of the devices are similar. Non-clinical performance data for software, cybersecurity, EMC, electrical safety, ingress protection, operational temperature and system reliability is included in this premarket notification to demonstrate that the subject device do not raise any new questions of safety and effectiveness compared to the predicate device. The proposed devices are at least as safe and effective as the predicate devices.
Conclusion	It is concluded that the information provided demonstrate the substantial equivalence of the subject devices to their predicate devices.